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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,136	07/18/2003	Jun Li	DD.1.0038.US2	5547

31629 7590 11/17/2006

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,136	LI ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16,46-56,70-82 and 84-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16,46-56,70-82 and 84-103* is/are rejected.

7)☒ Claim(s) *82* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/18/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/04/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Groups II in the reply filed on 10/04/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The amendment to the claims filed 10/04/2006 has been entered.

Claim Objections

Claim 82 is objected to because of the following informalities: Generally ranges should start from the numerically lower number to the higher one, therefore the range should read: 2,500 to 3,000 not "3,000 to 2,500" as currently claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12,46,80 and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12 and 46 only have support in the specification for the following poly(hydroxyalkanoates): poly[(R)-3-hydroxybutyrate] (PHB), poly[(R)-4-hydroxybutyrate] (PGHB); poly[(R)-3-

hydroxyvalerate] (PHV); poly[(R)-3-hydroxybutyrate]-co-poly[(R)-3-hydroxyvalerate] (PHB/HV); poly[(R)-3-hydroxyhexanoate] (PHHx); poly[(R)-3-hydroxyheptanoate] (PHHp); (R and S) enantiomers of each of the above; racemic mixtures of the above; and mixtures of the above poly(hydroxyalkanoate)s. The specifications does not give written support for all poly(hydroxyalkanoate)s as broadly claimed. Also claims 12 and 46 only have support in the specification for the following poly(alkylene oxides): poly(ethylene oxide), poly(tetramethylene oxide) and poly(tetrahydrofuran). The specification does not give written support for all poly(alkylene oxides) as currently broadly claimed. It is suggested by the examiner that applicants amend claims 12 and 46 to include the limitations of the poly(alkylene oxide)s in claim 13 and the PAOs in claim 14. The molecular weights in claims 80 and 82 have no support in the specification, the examiner only found support for the A block polymer with a MW of 500-2,000 or 2,000-10,000 and the B block polymer with a MW of 500-2,000 or 2,000-10,000 and 2,500-7,500 or 3,000-5,000.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-16,46-56,70-82 and 84-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koll et al. (US 6,346,274 B1) in view of Cha et al. (US 5,702,717, cited by applicant).

Koll discloses parenteral pharmaceutical forms of administration containing microparticles comprised of polypeptides embedded in ABA triblock copolymers wherein the A block is a copolymer of lactic and glycolic acid (a polyester) while the B block is PEG; additives can also be added such as cyclodextrins, the MW of the A and B block as well as the ABA copolymer are within applicants claimed range. See abstract, col 3 lin 56-col 4 lin 50, and lin 51-col 5 lin 51. Regarding claims 47-56 which are product by process claims, the claims are met because the combination of Koll and Cha disclose the same drug delivery system as applicants, the limitations are met because:"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Koll while disclosing ABA block copolymers comprised of PEG and polyesters such as lactic and glycolic acid does not disclose the use of the specific polyester poly(hydroxyalkanoate).

Cha discloses an injectable or implantable system for parenteral delivery of a polypeptide drug in a biodegradable polymeric matrix, the matrix comprises a biodegradable ABA or BAB block copolymer in which the A block is formed from hydroxybutyric acid with a MW between 1,000-5,000 and B comprises PEG with a MW between 1,000-10,000. See abstract, col 7 lin 39-col 8 lin 13. In addition to peptides other drugs were disclosed as useful in combination with the pharmaceutical composition including antibiotics, anti-inflammatories, anticancer agents ect. See col 10 lin 18-23. Regarding the limitation in claims 13,16,47-48,70,78-79 and 92 that the poly(hydroxyalkanoate) is a specific species such as poly[(R)-3-hydroxybutyrate], this limitation is considered met by the examiner even though the Cha reference states the A block is preferably a poly(α-hydroxy acid) which when PHB is used as the monomer would form poly[(R or S)-2-hydroxybutyrate]. The two polymers are positional isomers and are considered by the examiner to be so close in their structures to be obvious derivatives to one another with similar properties that are not patentably distinct from one another. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds

possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious). Regarding claim 98 on the limitation that the drug delivery system is administered topically, this limitation is met by Cha even though the preferred delivery method is parenteral because the patent discloses that gels comprised of block copolymers were well known to be used in topical drug delivery systems. Therefore it would have been obvious to the skilled artisan that the biodegradable polymeric matrix within Cha could be used in other routes of administration such as topical administration. Regarding claims 71 and 93, the copolymers and drug were dissolved in PBS buffer, which contains sodium phosphate and potassium phosphate two basses dissolved in water. See experimental.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Koll discloses all of applicants claimed invention but does not disclose the use of the specific polyester poly(hydroxyalkanoate) in the triblock copolymer while Cha discloses triblock copolymers comprised of PEG and poly(hydroxyalkanoates). The motivation to combine the above documents would be a drug delivery system comprised of cyclodextran and an ABA triblock copolymer of PEG and poly(hydroxyalkanoate). The first advantage of such a drug delivery system would be that the additive cyclodextran would reduce the tendency of microparticles to aggregate and cohere during their production. The second advantage would be by using an ABA block copolymer comprised of the hydrophilic portion PEG and a hydrophobic section

comprised of polyhydroxy acids such as poly(hydroxyalkanoate) is that the degradation rates could be controlled by varying the type of hydrobobic segments. One skilled in the art would by combining Koll with Cha would form a biodegradable polymeric drug delivery system with cyclodextrin as an additive to control aggregation and coherence of the microparticles during production and be able to control the degradation rates of the ABA copolymer by varrying the hydrophobic groups including poly(hydroxyalkanoates). Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER